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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,169	03/04/2002	Erkki Heinonen	2532-00290	9925
26753	7590	10/22/2003		
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202				

EXAMINER	
NATNITHADHA, NAVIN	
ART UNIT	PAPER NUMBER

3736

DATE MAILED: 10/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,169

Applicant(s)

HEINONEN ET AL.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-31 and 67-69 is/are allowed.
- 6) ☒ Claim(s) 32, 46, 52, 58 and 66 is/are rejected.
- 7) ☒ Claim(s) 33-45, 47-51, 53-57 and 59-65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on March 05, 2001. It is noted, however, that applicant has not filed a certified copy of the European application as required by 35 U.S.C. 119(b).

Drawings

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 32, 46, 53, 58, and 66, are rejected under 35 U.S.C. 102(b) as being anticipated by Yamakoshi, US 4,204,545 A.

In regards to claims 32, 46, 52, 58, and 66, Yamakoshi teaches an apparatus and method for determining a change in a measured condition of the circulatory system of a subject (see col. 4, lines 37-47), comprising: means for

non-invasively obtaining initial Y_0 and subsequent values for at least on selected variable capable of indicating changes in a measured circulatory system condition of the subject; means for carrying out a discrete measurement of a circulatory system condition of a subject; means for comparing subsequent value of the variable with the initial value of the variable to determine whether the obtained variable has changed in value (ΔY); and sequentially obtaining further values of the at least one selected variable for comparison with the initial value; and initiating an action responsive to a change in the variable (see col. 4, lines 40-52).

Allowable Subject Matter

4. Claims 1-31 and 67-69 are allowed.
5. Claims 33-45, 47-51, 53-57, and 59-65, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The following is a statement of reasons for the indication of allowable subject matter:

In regards to claims 1-31 and 67-69, the prior art does not teach a method for non-invasively determining a condition of the circulatory system of a subject, including the steps of: measuring the amount of CO_2 in the breathing gases exhaled by the subject and the CO_2 concentration of the breathing gases exhaled by the subject for two breathing conditions of the subject; determining at least one value of the amount of CO_2

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released from the circulatory system of the subject (VCO_2^1 and VCO_2^2) using the amount of CO_2 in the exhaled breathing gases for each breathing conditions; determining at least one value for a quantity indicative of the end capillary blood CO_2 content of the subject using the CO_2 concentration of the breathing gases exhaled when the subject is each condition; performing a regression analysis using the determined VCO_2^1 , VCO_2^2 , and end capillary blood CO_2 quantity values to establish a regression line; and extrapolating the regression line to obtain a value for the end capillary CO_2 quantity when the amount of CO_2 released from the circulatory system of the subject (VCO_2) is zero.

As to claims 33 and 59, the prior art does not teach the apparatus and method in claims 32 and 58, including wherein the selected variable comprises at least one of exhaled CO_2 amount, end tidal CO_2 amount, heart rate, and the amount of CO_2 released from the blood of the subject ($V CO_2$).

As to claims 34, 35, and 60, the prior art does not teach the apparatus and method in claims 32 and 58, including means for compensating the values of the selected indicator variable for changes in the condition of the subject not arising from circulatory system conditions.

As to claims 36-39, 40, 41, and 50, the prior art does not teach the apparatus and method in claim 32, including wherein the discrete measurement of circulatory system condition is carried out using Fick Equation 1 or 2 and the quantities expressed therein and the circulatory system condition is FCO or $PvCO_2$.

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As to claims 42-45, the prior art does not teach the apparatus and method in claim 32, including wherein the discrete measurement of the circulatory system condition is carried out using a blood dilution technique.

As to claims 47 and 48, the prior art does not teach the apparatus and method in claim 46, including obtaining further values on a breath-by-breath basis or a heart beat by heart beat basis.

As to claims 49 and 51, the prior art does not teach the apparatus and method in claim 32, including allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for the at least one selected variable; and determining whether the variable has changed by a predetermined amount.

As to claim 53-57, the prior art does not teach the apparatus and method in claim 52, including: initiating a further carrying out of a discrete measurement of a circulatory system condition of the subject; providing an indication that a change in the value of the variable has occurred; providing an indication of the amount by which the value of the variable has changed; providing an indication of the direction in which a change in the value of the variable has occurred; and providing an alarm.

As to claim 61-65, the prior art does not teach the apparatus and method in claim 58, including: the measured circulatory system condition is FCO, PvCO₂, or CO; and the measured circulatory system condition is measured non-invasively or invasively.


Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Navin Natnithithadha
Patent Examiner
GAU 3736
October 17, 2003


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
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